

**REMARKS**

Claims 13-16 are all the claims pending in the application.

Claims 13, 14 and 16 have been amended to make clear that the recited method is repeated on different portions of the DNA molecule. Support for the amendment may be found in the specification at page 5, line 23 through page 6, line 2, and in Example 1 (pages 15-17, see also Figure 1), where it is clear that the methods are repeated on different portions of the selected DNA molecule.

No new matter has been added. Entry of the Amendment is respectfully requested.

**I. Application Status**

A final office action was issued in this application on October 19, 2005. Applicants filed a Response Under 37 C.F.R. §1.116 on January 19, 2006, requesting reconsideration of the final office action. The Examiner issued an Advisory Action dated February 14, 2006, indicating that the Response did not place the application in condition for allowance.

In view of the Examiner's statements in the Advisory Action, the claims are being amended herein. In conjunction with the claim amendments, Applicants reiterate the traversing arguments set forth in the response filed January 19, 2006, with a slight variation in view of the claim amendments.

**II. Rejection of Claims Under 35 U.S.C. §102**

At page 3 of the Office Action, claims 13 and 16 are rejected under 35 U.S.C. §102(b) as being anticipated by Davey et al. (U.S. Patent No. 5,409,818, issued April 25, 1995).

At pages 3-5 of the Office Action, the Examiner sets forth the steps of Applicants' claim 13, and points to the location of support for each step in Davey. While the Examiner provides no additional comments, it appears that the Examiner considers each of the steps recited in claims 13 and 16 to be taught by Davey.

Claim 13 recites a method for determining whether a portion of a selected DNA molecule encodes a gene transcription region (as opposed to an intron or other non-coding sequence) via amplification of RNA transcripts using selected primers.

In the present Amendment, claims 13, 14 and 16 are being amended to include a step of repeating the amplification method on a different portion of the selected DNA molecule. Thus, as amended the method requires repeating the method on two different portions of a selected DNA molecule. Davey does not teach amplification of two different portions of a selected DNA molecule.

At page 5 of the Office Action, the Examiner indicates that she believes Davey does teach amplification of two different regions, citing to col. 3, lines 26-58, of the Davey.

Applicants respectfully traverse the Examiner's position for the following reasons. A close reading and understanding of Davey reveals that the patent only teaches repetition of the patented method on the same region of the same polynucleotide. Davey teaches the amplification of a single-stranded RNA molecule such that multiple copies of the same RNA molecule are produced. Indeed, as stated at col. 3 of Davey, lines 3-4, each cycle of the amplification "generates a plurality of copies of product from one substrate." Moreover, it is stated at col. 3, lines 5-7, that the amplification increases the quantity of "one specific nucleic

acid.” Davey further states that the claimed method can be used to increase the purity of a specific nucleic acid sequence (col. 3, lines 8-10).

While the Examiner cites to col. 3, lines 26-58, of Davey as support for her position that the amplification is repeated on other selected portions of the DNA molecule, Applicants respectfully assert that Davey does not support this position. In order for the amplification to be repeated on at least one different portion of the selected DNA molecule, primers corresponding to a second, different portion would need to be used. Further, a different RNA molecule would be amplified. It does not appear that Davey teaches either. Davey merely teaches repetition of the amplification process, using RNA molecules having the same sequence as the first template, and using the same primers. As such, the amplification is not being repeated on an RNA molecule corresponding to a second portion of the selected DNA molecule.

The Examiner’s interpretation of the phrase “a selected portion of” provided at page 2 of the Office Action supports this position. Therein, the Examiner states that the phrase “a selected portion of” is being interpreted as “any portion of any DNA sequence that has been selected by virtue of amplifying it.” Thus, a selected portion of a DNA sequence is one that has been amplified. Because the amended claims require amplification of a different portion of the selected DNA molecule, by virtue of the Examiner’s definition the claims require the amplification of at least two portions of a DNA sequence. In Davey, the patented method only teaches the amplification of one selected portion of a DNA sequence. As only one set of primers is used, and the method repeatedly amplifies one RNA sequence, and it is only one portion of a selected DNA sequence that is being amplified.

The claims of the pending application require the amplification of at least one other, different portion of the DNA sequence. Thus, the claims require amplification of two different portions of a DNA sequence. Indeed, as shown in Figure 1, the method is repeated on five different portions of a DNA sequence. As the method of Davey does not teach the amplification of at least two different portions of a selected DNA molecule, the method of Davey does not teach each element of the rejected claims and thus does not anticipate the claimed invention.

In addition, while the Examiner states that “Davey et al. teach a method for determining whether a selected DNA molecule encodes a gene expression region”, Applicants respectfully contend that Davey only teaches a method of amplifying a selected RNA molecule. There is no teaching or suggestion in Davey that the patented method could be used to determine whether a selected DNA molecule encodes a gene expression region.

In view of these comments, it is clear that Davey does not teach each and every limitation of the pending claims and thus does not anticipate these claims under 35 U.S.C. §102(b). Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

### **III. Rejection of Claims Under 35 U.S.C. §103**

At page 5 of the Office Action, claims 14 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Davey et al. in view of Wittwer et al. (U.S. Patent No. 6,503,720).

The Examiner repeats the position previously set forth in the Office Action dated January 4, 2005, namely that Davey teaches the method set forth in claims 14 and 15, with the exception that Davey does not teach all of step (c) of claim 14, that is, the use of an intercalating fluorescence dye. However, the Examiner contends that Wittwer teaches such dyes, and that it

would have been *prima facie* obvious to one of ordinary skill in the art to combine the method of Davey with the use of the dye of Wittwer.

Applicants incorporate herein the comments above concerning Davey, namely, that because Davey does not teach the amplification of at least two different portions of a selected DNA molecule, the method of Davey does not teach each element of the rejected claims.

Claim 14 has also been amended to include the step of repeating the amplification on at least one different portion of the selected DNA molecule. As Davey does not appear to teach this additional step, Davey does not teach or suggest the claimed method. Because Wittwer also does not teach the additional step, it also does not teach or suggest, alone or in combination with Davey, the claimed method.

In view of these comments, it is clear that the Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. §103(a) over Davey in view of Wittwer. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **IV. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. §1.114(c)  
U.S. Appln. No. 09/904,557

Q65441

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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